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BLEEDING WITH ASPIRIN AND APIXABAN IN PATIENTS UNSUITABLE FOR VITAMIN K ANTAGONIST THERAPY: THE AVERROES STUDY

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Background: Patients with AF unsuitable for VKA therapy often receive aspirin for stroke prevention. The factor Xa inhibitor apixaban has been shown to reduce stroke in AF patients and understanding the predictors of bleeding compared to aspirin is part of a benefit/risk assessment.

Methods: The Apixaban Versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who Have Failed or Are Unsuitable for Vitamin K antagonist Treatment (AVERROES) trial included 5599 patients with AF and risk factors randomized to either aspirin (81-324mg) or apixaban. Bleeding events (BE) included major bleeding and clinically relevant non-major bleeding.

Results: The annual risk of a BE was 3.77% with aspirin and 4.49% with apixaban. More superficial/hematoma/site puncture BE's occurred with aspirin, otherwise the anatomic site of bleeding did not differ between therapies. Multivariable predictors of a BE for aspirin included peripheral artery disease (HR 2.30; 95% CI 1.11-4.27, p= 0.03), daily/occasional nosebleeds (HR 2.47; 95% CI 1.26-4.42, p=0.01), non-study use of aspirin >50% of the time (HR 1.89; 95% CI 1.13-3.02, p= 0.02), baseline hemoglobin (HR 0.621; 95% CI 0.419-0.922, p= 0.02) and eGFR > 60ml/min vs. <60 ml/min (HR 0.66; 95% CI 0.44-0.98, p=0.04). Multivariable predictors of a BE for apixaban included age > 75 years (HR 1.60; 95% CI 1.10-2.32, p=0.01), daily/occasional nosebleeds (HR 2.10, 95% CI 1.11-3.65, p=0.02), and non-study aspirin > 50% of the time (HR 1.75; 95% CI 1.09-2.70, p=0.02). Models which predict major bleeding in AF patients were applied. For aspirin, Harrell's c-statistic for HAS-BLED, ATRIA the Shireman model, and CHADS2 was 0.63, 0.57, 0.60, and 0.54 respectively. For apixaban, Harrell's c-statistic was 0.64, 0.60, 0.61, and 0.58 respectively.

Conclusions: The risk of a BE in these patients is low with aspirin and apixaban. Except for superficial/hematoma/puncture site location, the bleeding site did not differ between therapies. Models which predict bleeding in AF patients have a low predictive value with aspirin and apixaban. We were unable to identify AVERROES patients with sufficiently high bleeding risk who would not benefit from apixaban over aspirin.